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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/412,947	10/05/1999	SUDHIR AGRAWAL	HYZ-050CP2	1312

7590 07/11/2005

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EXAMINER

EPPS FORD, JANET L

ART UNIT PAPER NUMBER

1633

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/412,947

Applicant(s)

AGRAWAL, SUDHIR

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 23-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 23-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/30/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 12-20, 39-43, 50, 53, 56 and 73-85 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 5,969,117 in view of Cho-Chung, (US Patent No. 5,271,941), Prewett et al. (1996), and DasGupta et al. (US Patent No. 5,658,947).

The claims of the instant application and those of the issued US Patent are both drawn to compositions comprising synthetic, modified oligonucleotides complementary to nucleic acid encoding protein kinase A subunit RI α , wherein said oligonucleotides are hybrid, inverted hybrid, or inverted chimeric oligonucleotides. The claims of the instant application differ from the claims of the copending application to the extent that the instant claims read on compositions further comprising a second therapeutic agent that comprises an active ingredient for cancer therapy, particularly wherein the second therapeutic agent is an antibody that binds EGFR or a cytotoxic agent selected from the group consisting of taxanes, platinum-derived agents, and topoisomerase II-selective drugs.

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It would have been obvious to one of ordinary skill in the art at the time of the instant invention, to modify the compositions of the copending application to comprise a second therapeutic agent that is an active ingredient for cancer therapy in the design of the invention set forth in the instant claims. One of ordinary skill in the art would have been motivated to make this modification since antisense targeting PKA RI α (*see US Patent No. 5,271,941; it is noted that the prior art does not teach the hybrid, inverted hybrid or inverted chimeric structures of the instant invention*), and the second therapeutic agents recited in the instant claims (See for example Prewett et al. (1996), and DasGupta et al. US Patent No. 5,658,947) are described in the prior art as being useful for inhibiting the proliferation of cancer cells. It would have been obvious to combine two agents that are known to be useful for inhibiting the proliferation of cancer cells with the expectation that a combination would be formed, wherein said combination would be expected to have the same properties as the individual agents, namely for use in the inhibition of the proliferation of cancer cells. See MPEP § 2144.06 which states: "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-20, and 23-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The instant claims are drawn to pharmaceutical compositions comprising a synthetic, modified oligonucleotide complementary to nucleic acid sequence GCCAGTGAGGAG-GCACGC (SEQ ID NO: 11) encoding N-terminal codons 8-13 of protein kinase A subunit RI α , and methods of use of said modified oligonucleotide for inhibiting proliferation of cancer cells, and treating cancer in an afflicted subject comprising administration of said synthetic, modified oligonucleotide. However, the term "complementary" as recited in the instant claims is defined in the following manner in the specification as filed: "[F]or purposes of the invention, the terms "oligonucleotide sequence that is complementary to a genomic region or an RNA molecule transcribed therefrom" and "oligonucleotide complementary to" are intended to mean an oligonucleotide that binds to the target nucleic acid sequence under physiological conditions, e.g., by Watson-Crick base pairing (interaction between oligonucleotide and single-stranded nucleic acid) or by Hoogsteen base pairing (interaction between oligonucleotide and double-stranded nucleic acid) *or by any other means* including in the case of a oligonucleotide binding to RNA, causing pseudoknot formation. Binding by Watson-Crick or Hoogsteen base pairing under physiological conditions is measured as a practical matter by observing interference with the function of the nucleic acid sequence."

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To the extent that Applicants have defined the term “complementary” as encompassing a mechanism of binding other than typical hydrogen bonding (i.e. Watson-Crick binding), it appears that Applicants are attempting to redefine the term in a manner that is not an art accepted meaning for the term “complementary.”

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “complementary” in claims 1-20 and 23-100 is used by the claim to mean “binding by any other means”, while the accepted meaning is “binding by means of hydrogen bonding.” The term is indefinite because the specification does not clearly redefine the term.

Moreover, to the extent that the breadth of the term “complementary” encompasses binding “by any other means,” and applicants have not clearly set forth what other means of binding is encompassed by this term, the skilled artisan could not interpret the metes and bounds of the claim so as to understand how to avoid infringement.

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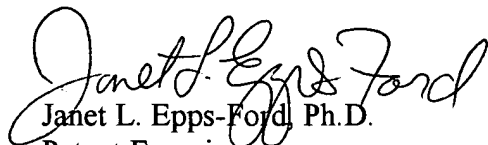
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571)272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


Janet L. Epps-Ford, Ph.D.
Patent Examiner
Art Unit 1633

JLE